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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,499	11/19/2003	Nathaniel E. David	110191.402	8232

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EXAMINER	
CARTER, CANDICE D	

ART UNIT	PAPER NUMBER
3629	

MAIL DATE	DELIVERY MODE
12/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,499	DAVID, NATHANIEL E.	
	Examiner	Art Unit	
	CANDICE D. CARTER	3629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Following is a Final Office Action in response to communications received on September 3, 2008. Claims 1, 11, 20, 21, 22, and 23 have been amended. No claims have been cancelled. Claim 26 has been added. Therefore, claims 1-26 are pending and have been addressed below.

Response to Amendment

2. Applicant has amended claim 22 and added claim 26 to overcome the claim objection with respect to claim 22. The claim objection of claim 22 is withdrawn. Applicant has also amended claim 11 to overcome its claim objection and the 35 U.S.C 112, second paragraph rejection. The claim objection and 35 U.S.C. rejection of claim 11 are withdrawn.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-26 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-26 recite the limitations: identifying an antibiotic, determining if bacteria develop resistance to the antibiotic, identifying an achaogen that is capable of decreasing the rate at which said bacteria mutates and selling the compound with an achaogen.

Examiner contends that a process must be (1) tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing.

An applicant may show that a process claim satisfies 35 U.S.C. § 101 either by showing that his claim is tied to a particular machine, or by showing that his claim transforms an article. See Benson, 409 U.S. at 70. Certain considerations are applicable to analysis under either branch. First, the use of a specific machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent eligibility. See Benson, 409 U.S. at 71-72. Second, the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity. See Flook, 437 U.S. at 590. *In re Bilski.*

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 11, 13-16, 20, 21, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hergenrother et al. (2003/0130169, hereinafter Hergenrother).

As per claim 1, Hergenrother discloses "A business method comprising:

identifying a compound that is effective as an antibiotic" (¶ 18 discloses that for treatments of drug resistant bacterial infections, the drug is selected from a group of antibiotics);

"determining if bacteria develop resistance to said compound whereby said compound would have decreased market potential because of, at least in part, said resistance" (¶ 14 discloses discovering methods to combat antibiotic resistant bacterial infections, where it is inherent that the bacteria has been determined to develop a resistance to the antibiotic);

"identifying an achaogen that is capable of decreasing the rate at which said bacteria mutates" (¶ 39 discloses mimicking the natural process of inhibiting the mutation rate of bacteria);

"And administering said compound with an achaogen" (¶ 16 discloses administering an antiplasmid composition with the antibiotic, where the antiplasmid composition is used to sensitize the bacteria to the antibiotic and where, the antiplasmid accomplishes the same goal as the achaogen).

Hergenrother, however, fails to explicitly disclose that the compound is sold with the achaogen.

Examiner takes **Official Notice** that it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the method of treating drug resistant bacterial infection of Hergenrother to include **the selling of an antibiotic with an achaogen** because it is old and well known to sell

antibiotics, drugs, or improvements thereof in order to make them accessible to the public.

For example, if a pharmaceutical company discovers a new drug or method of using a drug for treating an illness, they will sell it so as to make it commercial available to customers interested in treating the illness.

As per claim 11, Hergenrother discloses all of the elements of the claimed invention but fails to explicitly disclose "said biopharmaceutical company sells achaogen and said compound".

Examiner takes **Official Notice** that it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the method of treating drug resistant bacterial infection of Hergenrother to include **the selling of an antibiotic with an achaogen** because it is old and well known to sell antibiotics, drugs, or improvements thereof in order to make them accessible to the public.

For example, if a pharmaceutical company discovers a new drug or method of using a drug for treating an illness, they will sell it so as to make it commercially available to customers interested in treating the illness.

As per claims 13-16, and 24, Examiner considers a preclinical compound, a compound in clinical trials, a marketed compound, and an off-patent compound to be nonfunctional descriptive material as recited. The type of compound does not change the function of the claimed invention. Examiner contends that the methods of treating

drug-resistant bacterial infections of Hergenrother are fully capable of using or selling the recited compounds of claims 13-16 and 24. See rejection of claim 1 above.

As per claims 21-23 and 26, Examiner considers the specific type of achaogen used to be nonfunctional descriptive material as recited. The type of achaogen does not change the function of the claimed invention. Examiner contends that the methods of treating drug-resistant bacterial infections of Hergenrother are fully capable of using or selling the recited achaogens of claims 13-16 and 24. See rejection of claim 1 above.

6. Claims 2, 3, 6-10, 17, 19, 20, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hergenrother in view of Nurton (1999).

As per claim 2, Hergenrother discloses all of the elements of the claimed invention but fails to explicitly disclose "a biopharmaceutical company licensing rights from another organization to said compound".

Nurton discloses the role of intellectual property in pharmaceutical deals where a biopharmaceutical company licenses rights from an organization to particular drugs (pg. 2, ¶ 4, discloses licensing patent rights in order to develop a commercial product).

Therefore, it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the methods of treating drug-resistant bacterial infections to include the licensing of patent rights as taught by Nurton in order to develop a commercial product without infringement issues.

As per claim 3, Hergenrother discloses administering an achaogen with a compound (¶ 16 discloses administering an antiplasmid composition with the antibiotic,

where the antiplasmid composition is used to sensitize the bacteria to the antibiotic and where, the antiplasmid accomplishes the same goal as the achaogen.

Hergenrother, however, fails to explicitly disclose that the compound is sold with the achaogen. It would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the method of treating drug resistant bacterial infection of Hergenrother to include the selling of an antibiotic with an achaogen because it is old and well known to sell antibiotics, drugs, or improvements thereof in order to make them accessible to the public.

Hergenrother, also, fails to disclose “a biopharmaceutical company collecting royalties from a pharmaceutical company that sells a product".

Nurton discloses the role of intellectual property in pharmaceutical deals involving the collection of royalties (pg. 2, ¶ 4, discloses royalty streams).

Therefore, it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the method of treating drug resistant bacterial infections of Hergenrother to include the collection of royalties as taught by Nurton in order to compensate the patent owners for using their intellectual property.

As per claim 6, Hergenrother discloses performing experiments to identify said achaogen (abstract discloses identifying compositions by screening methods, where the screening methods are a form of experimentation).

Hergenrother, however, fails to explicitly disclose a biopharmaceutical company performing the experimentation.

Nurton discloses the role of intellectual property in pharmaceutical deals where the biopharmaceutical company performs experimentation (pg. 2, ¶ 7 discloses biopharmaceutical companies performing research to identify new drugs).

Therefore, it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the methods of treating drug resistant bacterial infections of Hergenrother to include that the experimentations were performed by the biopharmaceutical company as taught by Nurton in order to ensure that proper experimentation is performed.

As per claim 7, Hergenrother discloses all of the elements of the claimed invention but fails to explicitly disclose “biopharmaceutical company performs said experiments for a pharmaceutical company that has the right to sell said compound".

Nurton discloses the role of intellectual property in pharmaceutical deals where the biopharmaceutical company performs said experiments for a pharmaceutical company that has the right to sell antibiotics (pg. 2, ¶ 6 and 7 discloses biopharmaceutical companies performing research to identify new drugs, where these companies receive funding from pharmaceutical companies who currently have the right to sell antibiotics).

Therefore, it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the methods of treating drug resistant bacterial infections of Hergenrother to include the biopharmaceutical company performing said experiments for a pharmaceutical company that has the right to sell

antibiotics as taught by Nurton in order to ensure that proper experimentation is performed.

As per claim 8, Hergenrother discloses all of the elements of the claimed invention but fails to explicitly disclose "pharmaceutical company pays research fees to said biopharmaceutical company".

Nurton discloses the role of intellectual property in pharmaceutical deals involving the payment of research fees (pg. 2, ¶ 6 discloses research costs and overhead).

Therefore, it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the methods of treating drug resistant bacterial infections of Hergenrother to include the payment of research fees as taught by Nurton in order to compensate the biopharmaceutical company for all research performed and to fund future research.

As per claim 9, Hergenrother discloses all of the elements of the claimed invention but fails to explicitly disclose "pharmaceutical company pays royalties to said biopharmaceutical company for sales of said compound".

Nurton discloses the role of intellectual property in pharmaceutical deals involving the collection of royalties (pg. 2, ¶ 4, discloses royalty streams).

Therefore, it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the method of treating drug resistant bacterial infections of Hergenrother to include the collection of royalties as taught by Nurton in order to compensate the patent owners for using their intellectual property.

As per claim 10, Hergenrother discloses “identifying said achaogen for use with said compound (abstract and ¶ 16 discloses administering an antiplasmid composition with the antibiotic, where the antiplasmid composition is used to sensitize the bacteria to the antibiotic and where, the antiplasmid accomplishes the same goal as the achaogen).

Hergenrother, however, fails to explicitly disclose "a biopharmaceutical company licenses or acquires said compound from a pharmaceutical company".

Nurton discloses the role of intellectual property in pharmaceutical deals involving licensing or acquiring drugs (pg. 3, ¶ 4 discloses that developing a commercial product involves either licensing in or merging, where merging is acquiring).

Therefore, it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the methods of treating drug resistant bacterial infections of Hergenrother to include the licensing or acquiring of antibiotics as taught by Nurton in order to avoid infringement issues.

As per claim 17, Hergenrother discloses all of the elements of the claimed invention but fails to explicitly disclose “patenting a new combination of an achaogen and said compound”.

Norton discloses the role of intellectual property in pharmaceutical deals involving the patenting of drugs (pg. 6, ¶ 3 disclose obtaining patent ownership).

Therefore, it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the methods of treating drug resistant

bacterial infections of Hergenrother to include the patenting of pharmaceutical products as taught by Nurton in order to protect intellectual property.

Claim 25 recites equivalent limitations to claim 17 and is, therefore, rejected using the same art and rationale as set forth above.

As per claim 19, Hergenrother discloses identifying said achaogen for use with said compound (abstract and ¶ 16 discloses administering an antiplasmid composition with the antibiotic, where the antiplasmid composition is used to sensitize the bacteria to the antibiotic and where, the antiplasmid accomplishes the same goal as the achaogen).

Hergenrother, however, fails to explicitly disclose "a biopharmaceutical company licenses said compound from a pharmaceutical company and pharmaceutical company licensing the use of the compound with the achaogen".

Nurton discloses the role of intellectual property in pharmaceutical deals involving the licensing of pharmaceutical products (pg. 3, ¶ 4 discloses that developing a commercial product involves either licensing in or merging).

Therefore, it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the methods of treating drug resistant bacterial infections of Hergenrother to include the licensing of drugs as taught by Nurton in order to avoid infringement issues.

The Hergenrother and Nurton combination, however, fails to explicitly disclose that a biopharmaceutical company licenses said compound from a pharmaceutical

company and pharmaceutical company licensing the use of the compound with the achaogen.

It would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the methods of treating drug resistant bacterial infections of the Hergenrother and Nurton combination to include a biopharmaceutical company licensing said compound from a pharmaceutical company and pharmaceutical company licensing the use of the compound with the achaogen because fragmentation of patent rights is old and well known in the art and in order to profit from products that are owned by another company, companies must either acquire the product or license-in.

As per claim 20, Examiner considers the recited method of performing the experiments is nonfunctional descriptive material. The type of experiments performed by the biopharmaceutical company does not change the function of the claimed invention. The chosen method of performing the experiments to identify drug resistant bacteria does not affect the overall method of identifying the compound, determining if there is a resistance, and selling the compound with an achaogen. Examiner contends that the methods of treating drug-resistant bacterial infections of the Hergenrother and Nurton combination are fully capable of using the recited experimentation methods. See rejection of claim 6 above.

7. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hergenrother in view of Business Wire (2000).

As per claim 4, Hergenrother discloses all of the elements of the claimed invention but fails to explicitly disclose "collecting fees from a pharmaceutical company".

Business Wire discloses pharmaceutical agreements involving the collection of fees (abstract discloses patent license fees).

Therefore, it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the methods of treating drug resistant bacterial infections of Hergenrother to include the collection of fees as taught by Business Wire in order to compensate patent owners for using their intellectual property.

As per claim 5, Hergenrother discloses all of the elements of the claimed invention but fails to explicitly disclose "wherein said fees comprise at least one of license fees and milestone fees".

Business Wire discloses pharmaceutical agreements involving the collection of fees (abstract discloses patent license fees and conditional milestones).

Therefore, it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the methods of treating drug resistant bacterial infections of Hergenrother to include the collection of fees as taught by Business Wire in order compensate patent owners for using their intellectual property.

8. Claims 12 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hergenrother in view of Nurton and further in view of Business Wire.

As per claim 12, the Hergenrother and Nurton combination discloses all of the elements of the claimed invention but fails to explicitly disclose "licensing a selling company to sell said compound with said achaogen".

Business Wire discloses pharmaceutical agreements involving the licensing of drugs to a selling company to sell pharmaceutical products (abstract discloses IDEC and Taisho obtaining commercialization rights to pharmaceutical products through licensing).

Therefore, it would have been obvious to one of ordinary skill in the pertinent art at the time the invention was made to modify the methods of treating drug resistant bacterial infections of the Hergenrother and Nurton combination to include the licensing of a selling company to sell pharmaceutical products as taught by Nurton in order to avoid infringement issues.

Claim 18 recites equivalent limitations to claim 12 and is, therefore, rejected using the same art and rationale as set forth above.

Response to Arguments

9. Applicant's arguments filed September 3, 2008 have been fully considered but they are not persuasive.

In response to arguments for the 35 U.S.C 101 rejections of claims 1-26, Examiner respectfully disagrees. Applicant's invention is not tied to machine and may be completed by a series of mental steps. As such, Applicant's claims do not constitute a statutory process. Examiner maintains this rejection

Applicant's arguments with respect to claims 1, 11, 13-16, and 20 have been considered but are moot in view of the new ground(s) of rejection.

In response to arguments in pertaining to claims 21 and 23 and amended claims 22 and 26, Examiner respectfully disagrees. The listed types of achaogens do not constitute functional limitations because they are not recited as having any added functionality other than what is already encompassed in the functionality of an achaogen, therefore, the specific type of achaogen does not change the function of the claimed invention. Examiner maintains this rejection.

In response to arguments in reference to claims 2-10, 12, 17-19, and 25 all rejections made towards the dependent claims are maintained due to a lack of reply by the applicant in regards to distinctly and specifically pointing out the supposed errors in the examiner's prior office action (37 CFR 1.111). The Examiner asserts that the applicant only argues that the dependent claims should be allowable because the independent claims are unobvious and patentable over the prior art.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Brindavanam et al. (6,599,541) discloses composition for treatment of drug resistant bacterial infections. Carrier (2003) discloses resolving the patent anti-trust paradox.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CANDICE D. CARTER whose telephone number is (571) 270-5105. The examiner can normally be reached on Monday thru Thursday 7:30am- 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss can be reached on (571) 272-6812. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. D. C./
Examiner, Art Unit 3629

/John G. Weiss/
Supervisory Patent Examiner, Art Unit 3629